



NORTH DAKOTA DEPARTMENT OF HEALTH
Division of Air Quality

**RADIOACTIVE MATERIAL
LICENSING GUIDE**

Portable Gauging Devices

(Revised February 2006)

I. INTRODUCTION

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of radioactive material contained in portable gauging devices such as moisture-density gauges and X-ray fluorescence analyzers. The Department's rules (North Dakota Radiological Health Rules), listed below, apply to radioactive material licensees and should be used in conjunction with this guide. The applicant should carefully read the rules. This guide does not substitute for an understanding of the rules.

- A. Chapter 33-10-01, "General Provisions"
- B. Chapter 33-10-03, "Licensing of Radioactive Material."
- C. Chapter 33-10-04.1, "Standards for Protection Against Radiation."
- D. Chapter 33-10-10, "Notices, Instructions and Reports to Workers - Inspections."
- E. Chapter 33-10-11, "Fees for Issuance of License and Registration Certificates and Inspections."
- F. Chapter 33-10-13, "Transportation of Radioactive Material"

All information submitted as part of this application will be subject to North Dakota's Open Record Statute, Section 44-04-18, "Access to public Records - Penalty" of the North Dakota Century Code. The information will be available to the public unless confidentiality is granted by the Department. Requests for confidentiality must be submitted in accordance with Section 23-20.1-09.1, "Confidentiality of Records" of the North Dakota Century Code. Confidentiality requests will be considered in accordance with the above-mentioned statutes.

II. FILING AN APPLICATION

The information submitted must be sufficient to allow the Department to determine that the proposed equipment, facilities, procedures, and controls are adequate to protect health and minimize danger to life and property. Information submitted should pertain to the specific activities for which authorization is sought and should be complete. Submission of incomplete information may result in delays because of the correspondence necessary to obtain supplemental information. Applications should be mailed to:

North Dakota Department of Health
Division of Air Quality 2nd Floor
918 East Divide Ave.
Bismarck, North Dakota 58501-1947

Since licensees are required to comply with Department rules, license conditions, and the content of the submitted application, at least one copy of all information submitted to the Department should be kept by the applicant for reference.

III. RADIOACTIVE MATERIAL LICENSE APPLICATION FORM SFN 8418

The application (SFN 8414) should be completed following the instructions provided with the form. The signed original copy should be filed with the Department and one copy kept by the applicant. Since the space provided on the form is limited, additional sheets should be appended as necessary. Supplemental information should be labeled to

identify the applicant and should reference the item for which information is being given. The following comments deal with the indicated items:

Item 1 - Applicant and Locations of Use: The applicant corporation or other legal entity should be specified by name and mailing address in Item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

The actual sites of use should be given in 1(b). Permanent facilities such as field office storage areas for the gauges or devices should be identified in 1(b) by street address, city, and state. In addition, field locations of use should be specified as "temporary job sites." It is required that a licensee maintain a permanent in-state facility.

Attach additional sheets if more space is needed.

Items 2 and 3 - Self-Explanatory

Item 4 - Personnel: Each person who will use radioactive material should be named and his/her training and experience qualifications provided as explained in Items 8 and 9.

Item 5 - Radiation Safety Officer: If multiple users will be listed in Item 4, a radiation safety officer should be named in Item 5.

A statement should be included with the application outlining the duties and responsibilities of the RSO. The radiation safety officer is expected to coordinate the safe use of the nuclear gauging devices and to ensure compliance with the North Dakota State Radiological Health Rules and applicable U.S. Department of Transportation Regulations. Typical duties of the radiation safety officer should include:

- A. To assure that radioactive materials possessed under the license conform to the materials listed on the license.
- B. To assure that use of the devices, particularly in the field, is only performed by individuals authorized by the license.
- C. To assure that all users wear personnel monitoring equipment, such as film badges or thermoluminescent dosimeters (TLD), when required.
- D. To assure that gauges are properly secured against unauthorized removal at all times when they are not in use.
- E. To serve as a point of contact and give assistance in case of emergency (gauge damage in the field, fire, theft, etc.) to assure that proper authorities, for example, local police, and the State Health Department, are notified promptly in case of accident or damage to gauges.
- F. To assure that the terms and conditions of the license, such as periodic leak tests, and physical inventories are met and that the required records, such as personnel exposure records, leak test records, etc., are periodically reviewed for compliance with Department rules, requirements, and license conditions.

Item 6 - Radioactive Material:

- A. Identify each radioisotope that will be used in the gauging device.

- B. Identify the manufacturer and model number of each sealed source that will be used in the gauging device.
- C. Specify the amount of radioactive material that will be in each sealed source.

Item 7 - Uses: The manufacturer's name and model number of each gauge or device utilizing the sources listed in Item 6 must be specified and keyed to the listed source. In addition, specify the purpose for which the gauges will be used. For example, "Moisture-density gauges to be used for measuring moisture and surface density of construction materials."

Item 8 & 9 Qualifications of Personnel: The training and/or experience of each person who will use the gauges or devices or who will have radiological safety responsibilities should be submitted as indicated in Items 4 and 5 above. The qualifications of users and radiation safety personnel should be commensurate with the proposed use.

- A. Each person using the gauges or devices must have:
 - (1) Successfully completed the device manufacturer's training course or any other training course approved by this Department for gauge users.
 - (2) Been instructed in your operating and emergency procedures.
 - (3) Been designated as an authorized user of the gauges or devices by the Radiation Safety Officer.

Confirm that you will comply with this requirement.

- B. Hazmat Employee Training. Each person using or transporting the gauges or devices must comply with the hazmat employee training requirements in U.S. Department of Transportation regulation 49 CFR Part 172, Subpart H, "Training." Information on the training requirements is available on the internet at: <http://hazmat.dot.gov/training/training.htm> under the heading "Training Requirements Under the Hazardous Materials Regulations (HMR)." These include free "Hazmat Transportation Training Modules."

The "Hazmat Transportation Training Modules" provide general awareness/familiarization training; you must also provide function-specific training and safety training to fully comply with the training requirements.

Confirm that you will comply with this requirement.

- C. Driver Training. Each person who operates a vehicle while transporting a gauge or device must comply with the U.S. Department of Transportation requirements in 49 CFR 177.816, "Driver Training." However, this training is not required if the gauge or device is transported as an excepted package, such as one that conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package - instruments or articles, UN2910.

Confirm that you will comply with the driver training requirement or confirm that each gauge or device will be transported as an excepted package and will meet the requirements of 49 CFR 173.424 or another excepted package regulation.

Note: Much, or all, of the driver training requirement may be met by studying the North Dakota Commercial Drivers License Guide and documenting that this has been done.

D. Instructions to Workers. Gauge or device users:

- (1) Must be kept informed of the storage, transfer, or use of sources of radiation.
- (2) Must be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.
- (3) Must be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the North Dakota Radiological Health Rules and licenses for the protection of personnel from exposures to radiation or radioactive material
- (4) Must be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of North Dakota Century Code chapter 23-20.1, the North Dakota Radiological Health Rules, and licenses or unnecessary exposure to radiation or radioactive material.
- (5) Must be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.
- (6) Must be advised as to the radiation exposure reports which workers must be furnished.

Confirm that you will comply with this requirement.

E. Radiation Safety Refresher Training. Radiation safety refresher training should be provided annually to all nuclear gauge users. Such training typically lasts 1-4 hours, may be provided by your Radiation Safety Officer or by other trainers such as radiation safety officers at universities, and typically covers such topics as incidents and accidents, changes to regulations, health effects of radiation, radiation safety practices, and other radiation safety topics.

Confirm that radiation safety refresher training will be provided annually to all gauge users. If the applicant desires to provide in-house training for his own personnel, a description of the training must be provided. The description of the in-house training should include:

- (1) The name(s), training and experience of the individual(s) providing formal training.
- (2) An outline of the formal training and on-the-job training to be provided, including the duration of the training.
- (3) The means of determining when the trainee has satisfactorily completed the training and is capable of carrying out the radiation safety responsibilities required by the license.

Items 10 & 11 Radiation Detection Instruments: Each year there are a number of incidents involving nuclear gauges, such as transportation accidents or construction equipment running over gauges. As soon as possible after an incident, a radiation

survey meter should be used to determine the location of the radioactive source, whether the shielding and radioactive sources are intact and whether personnel or equipment are contaminated with radioactive material. For this reason, gauge licensees must either possess or have ready-access to a calibrated radiation survey meter.

At a minimum, the radiation survey meter must:

- Be capable of detecting gamma radiation.
- Be capable of measuring from 0.01 to 0.5 mSv/hr (1 to 50 millirem per hour).
- Be calibrated at least annually by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to calibrate radiation detection instruments. Calibration records must be kept at least three years.
- Be checked for functionality before each use, such as with a nuclear gauge or a check source.

Please specify how you will obtain a radiation survey meter that will meet the specifications listed above.

Lists of manufacturers are available from this Department or on the internet at <http://www.thomasregister.com> or <http://www.crcpd.org> (look under "free documents" and then "commercial services").

Other possible options include borrowing a calibrated radiation survey meter that meets the above specifications from a consultant, from your company's home office, or from a local emergency response organization.

If radiation survey meters are necessary for the proposed activity, survey meter calibration provisions should be described. If the applicant intends to contract out the calibration of instruments, the name, address and license number of the calibration firm should be specified together with the frequency of the calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Department. If information has not been filed, information concerning calibration procedures should be obtained and submitted.

If the applicant intends to perform the survey instrument calibrations, state the frequency and describe the methods and procedures for performing the calibrations.

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instrument function should be supplemented every six months with a two-point calibration on each scale of each instrument with the two points separated by at least 50 percent of the maximum scale divisions. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for the points checked. Readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

The description of applicant's calibration procedures should include, as a minimum:

- A. The manufacturer and model number of each radiation source to be used,
- B. The nuclide and quantity of radioactive material contained in the source,
- C. The accuracy of the source(s). (The traceability of the source to a primary standard should be provided),
- D. The step-by-step procedures for calibration, including associated radiation safety procedures, and
- E. The name(s) and pertinent experience of person(s) who will perform the calibrations.

Item 12 - Personnel Monitoring: Personnel using gauges are required to wear personnel monitoring devices such as film badges, thermoluminescent dosimeters (TLD) or other Department approved monitoring badges. Specify the type of badge, the frequency of exchange and the name and address of the supplier of monitoring badge.

Item 13 - Facilities and Equipment: The key elements for portable gauge applicants are ensuring compliance with public dose limits, keeping radiation exposures as low as reasonably achievable, and maintaining adequate security and control over the gauges.

- A. Description of Gauge Storage Area. Include sketches that show the storage area, and any other areas nearby (including areas above, below, and on all sides of the storage area). Show and describe any areas near the storage area that are frequently occupied by people. Describe shielding that you will use to ensure that radiation levels are as low as reasonably achievable (ALARA).

- B. Public Dose. Licensees must do the following:

Ensure that licensed gauges are used, transported, and stored in such a way that members of the public will not receive more than 1 millisievert (100 millirem) in one year, that the dose in any unrestricted area will not exceed 0.02 millisievert (2 millirem) in any one hour from licensed operations, and that radiation doses to the public will be kept as low as reasonably achievable. Demonstrate through measurements or calculations that these limits will not be exceeded.

Control and maintain constant surveillance over gauges that are not in storage and secure stored gauges from unauthorized removal or use. State how you will comply with this requirement.

Members of the public include persons who live, work, or may be near locations where portable gauges are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored.

Operating and emergency procedures regarding security and surveillance should be sufficient to limit the exposure to the public during use or storage and after accidents. Public dose is controlled, in part, by ensuring that gauges not in use are stored securely (e.g., stored in a locked area) to prevent unauthorized access or use. If gauges are not in storage, then authorized users must maintain constant surveillance to ensure that members of the public, who could be co-workers, cannot get near the gauges or use them, and thus receive unneeded radiation exposure.

Public dose is also affected by the choice of storage location and conditions. Because a gauge office, the exterior surface of an outside wall, or occupied areas of a personal residence) does not exceed 1 millisievert (100 millirem) in a year or 0.02 millisievert (2 millirem) in any one hour. Licensees should take time, distance, and shielding into consideration when choosing a permanent or temporary storage location. Decreasing the time spent near a gauge, increasing the distance from a gauge, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce radiation exposure. As a rule of thumb, gauges should be stored as far away as possible from areas that are occupied by other employees and members of the public, and shielding should be used to ensure that radiation levels are as low as reasonably achievable.

Licensees can determine the radiation levels adjacent to the storage location either by calculations, a combination of direct measurements and calculations using such information as the typical known radiation levels provided by the manufacturer and the "inverse square" law to evaluate the effect of distance on radiation levels or by placing area dosimeters.

After making an initial evaluation, a licensee may make changes affecting the storage area (e.g., changing the location of the gauges within the storage area, removing shielding, adding gauges, changing the occupancy of adjacent areas, moving the storage area to a new location) but the licensee must ensure that gauges are properly secured, perform a new evaluation to ensure that the public dose limits are not exceeded, amend their license and take corrective action, as needed.

C. Security

Describe in detail how you will ensure against unauthorized removal or unauthorized use of the nuclear gauges - at your facility, while the gauges are being transported, and while the gauges are at field locations. To avoid lost or stolen gauges, licensees must keep the gauges under constant surveillance or secured against unauthorized use or removal.

Confirm that the gauge storage area at your facility will always be locked to prevent unauthorized access and that keys or combinations will be tightly controlled.

Confirm that when a gauge is transported, the source will be locked in the shielded position, the gauge will be inside the gauge transport package and the gauge transport package will be locked, the transport package will be blocked and braced to prevent movement during transportation, the transport package will be locked to the vehicle, or the transport package will be kept in a covered vehicle compartment (not in the open bed of a pickup).

Confirm that when the gauge is at a temporary job site but is not in use, the gauge source will be locked in the shielded position, the gauge will be inside the gauge transport package and the gauge transport package will be locked, and the gauge will be in a secured storage location (e.g., locked in the trunk of a car or locked in a storage shed with tightly controlled access).

Item 14 - Radiation Protection Program: Procedures should be established to ensure compliance with the provisions of Chapter 33-10-10, "Notices, Instructions and Reports to Workers - Inspections," and 33-10-04.1, "Standards for Protection Against Radiation".

A. The applicant should submit a copy of their written radiation safety and emergency procedures provided to their users of the gauges or devices, such as:

- (1) Safety measures to be used in transporting the devices in the applicant's vehicle (for example, fully secured within the transportation vehicle and away from the passenger compartment). Transportation activities must be carried out in accordance with the Department of Transportation Regulations.
- (2) Means of preventing unauthorized access to, and use or removal of gauges from temporary job sites. Instructions should state that individual users are never to leave gauges unattended.
- (3) Means of preventing unauthorized use or removal of gauges from the designated place(s) of storage at permanent locations and at temporary job sites.
- (4) Emergency procedures to be followed in case of accidents involving damage or loss of the gauges or devices, including names and telephone numbers of the individual(s) within the applicant's organization who should be notified and who would, in turn, notify the local police and the Department.
- (5) Specific measures to be followed to ensure that a physical inventory of all sealed sources received and possessed under the license is conducted every six months.
- (6) Specific instructions to the users informing them that any maintenance or repair on the gauges involving dismantling, removal of source holder(s), etc., must not be performed by the user and must only be performed by the manufacturer of the device, unless the applicant has specifically requested authority for performing maintenance in the application.
- (7) ALARA:

Ensuring that Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)

Describe the management policy and organizational structure related to ensuring that occupational radiation exposures are ALARA. Describe the applicable responsibilities and the related activities to be conducted by the individuals having responsibility for radiation protection. Indicate whether, and if so how, the guidance given in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," will be followed.

Please describe special measures that will be undertaken to limit exposure for female employees of child-bearing ages.

The application should contain a commitment by the applicant that all safety-related operations will be conducted in conformance with detailed written procedures. A detailed description of the procedures should be provided.

B. If the applicant wishes to be authorized to perform maintenance and repair on gauges and devices involving access to the source holders, and/or dismantling of

the shielding or shutter devices, specific information on the step-by-step procedures to be followed including radiation safety precautions must be supplied. In addition, the names of the personnel and the specific pertinent training of the personnel who will be performing such maintenance and repair must be given.

These applicants must provide all of the information specified in Appendix G of the "Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance", of U.S. Nuclear Regulatory Commission NUREG-1556, Volume I, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses". That document may be obtained at the NRC website:

<http://www.nrc.gov.edgesuite.net/reading-rm/doc-collections/nuregs/staff/sr1556/>

- C. In addition to the items listed above concerning the applicant's radiation safety program, the applicant must also describe the means of performing the required six-month leak testing of the sealed sources requested in the application. If the applicant plans to use a leak test kit, the name of the manufacturer and the manufacturer's model number of the leak test kit must be supplied. If the applicant desires to perform his own leak tests and not use a leak test kit, the following information should be submitted:

- (1) The name(s) and qualifications of personnel who will perform the leak test.
- (2) The safety procedures to be followed during the testing to minimize exposure to personnel.
- (3) The test procedures and materials to be used.
- (4) The type and the manufacturer's name and model number of the instrument to be used to assay the test sample. The test must be capable of detecting the presence of 185 Becquerels (0.005 microcurie) of contamination.

Item 15 - Waste Disposal: In the event the sealed sources will no longer be needed, the applicant should specify his means of disposal. Sealed sources containing radioactive material may be returned to the manufacturer, transferred to another licensee authorized to possess the specific quantity and form being transferred, or transferred to a licensed waste disposal firm.

IV. AMENDMENT AND RENEWAL OF LICENSES

Applicants for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requesting changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. If an application for license renewal is filed thirty days or more before license expiration, the existing license remains in effect until the new application has been finally acted upon by the Department.

Renewal applications should be filed using Form SFN 8418 and should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document

by date and indicate pertinent information by page and paragraph. There is no fee associated with the license renewal process.

For an amendment to an existing license the fee is \$115. The annual fee for a portable XRF license is \$500, and must be paid by January 1 each year the license is active. Fee payments shall be made by check, draft, or money order made payable to the North Dakota Department of Health. Fees are nonrefundable.